UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,029	02/11/2005	Morten Sloth Weidner	030307-0267	2260

22428 7590 08/23/2007
FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
BLAND, LAYLA D	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
08/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/512,029	WEIDNER, MORTEN SLOTH	
	Examiner	Art Unit	
	Layla Bland	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *58-61 and 64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *58-61 and 64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/22/2004, 12/05/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a national stage entry of PCT/DK03/00263, filed April 22, 2003, and claims priority to Denmark Application No. 2002-00586, filed April 19, 2002, and U.S. Provisional Application No. 60/373,615, filed April 19, 2002. Applicant's election of Group I, claims 54-64 and species salbutamol, and cancellation of claims 1-57, 62, 63, and 65-80, dated July 23, 2007, is acknowledged. Claims 54-64 are pending in this application and are examined on the merits herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58-61 and 64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising the specific beta-2 adrenoceptor agonists presented in claim 59, does not reasonably provide enablement for compositions comprising any beta-2 adrenoceptor agonist. This is a functional distinction or functional language. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states,

"Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a composition comprising a beta-2 adrenoceptor agonist and an aminosugar. The specification defines "beta-2 adrenoceptor agonist" as any component with the ability to stimulate a beta-2 adrenoceptor or parts thereof," and "the agonistic activity of a compound towards beta-2 adrenoceptor may be investigated by methods known to the person skilled in the art." Thus, the claims taken together with the specification imply that the invention is drawn to an aminosugar and any component

with the ability to stimulate a beta-2 adrenoceptor or parts thereof, including compounds not yet known in the art.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

A number of beta-2 adrenoceptor compounds are known in the art and are typically used to treat asthma. According to the 2006 Chemical Abstracts catalog, the Chemical Abstracts Registry contains entries for more than 26 million organic and inorganic substances, of which very few are known definitively either to be or not to be beta-2 adrenoceptor agonists. The existing literature does not identify any general method by which this class of compounds can be identified across all classes of molecular entities claimed other than by synthesizing and testing each one.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for the production of compositions comprising an aminosugar and the beta-2 adrenoceptor agonists presented in claim 59.

However, the specification does not provide guidance for the production of compositions comprising an aminosugar and presently unnamed beta-2 adrenceptor agonists. In order to make compositions across the full scope of these claims, the skilled artisan would be required to synthesize and test an essentially infinite number of compounds.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the state of the prior art and the high unpredictability in the

art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58-61 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 58-61 and 64 recite the limitation "wherein the amino group and/or hydroxyl group of the aminosugar is alkylated, arylated or acylated." It is unclear which hydroxyl group or groups may be alkylated, arylated or acylated. The specification does not define alkylated, arylated or acylated, so it is unclear, for example, the length of alkyl chain which may be present and if the alkyl chain may be substituted. It is unclear what "acyl" encompasses. Although "acyl" is presumed to mean that a carbonyl group is attached to the sugar, it is not clear what other attachment may be present on the carbonyl group. "Aryl" is also unclear as to ring size and substitution. Given the lack of definition of these terms, it is impossible to determine the metes and bounds of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 58-60 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Fleischner (US 2002/0136782 A1, published September 26, 2002, filed January 18, 2001).

Fleischner teaches a weight loss tablet comprising glucosamine sulfate and Ma huang extract (ephedrine alkaloids) [0016 and claims 3 and 4].

Claims 58-60 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Fleischner (US 6,420,350 B1, July 16, 2002, filed August 13, 2001).

Flesichner teaches a weight loss tablet comprising glucosamine sulfate and Ma huang extract (ephedrine alkaloids) [column 3, lines 35-50] and a composition comprising glucosamine and ephedrine [claim 3].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 58-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theoharides et al. (British Journal of Pharmacology 2000; 131, 1039-1049) and Rossi et al. (Chest 1997; 112; 523-529) in view of Wikipedia (Salbutamol).

Theoharides et al. teach that glucosamine sulfate and N-acetyl glucosamine inhibit activation of mast cells [page 1042, Table 2].

Rossi et al. teach that mast cells have a significant contribution to asthma [page 527, conclusions].

Neither Theoharides et al. nor Rossi et al. teach a composition comprising an aminosugar and a beta-2 adrenoceptor agonist.

Salbutamol is a beta-2 adrenoceptor agonist which is used to treat asthma and has been known since 1969, as taught by Wikipedia. Salbutamol is usually given though an inhaler but can also be given orally or intravenously.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition comprising glucosamine sulfate or N-acetyl glucosamine and salbutamol or other asthma medication. Salbutamol is a known asthma medication and glucosamine sulfate (and N-acetyl glucosamine) have been shown to inhibit activation of mast cells, which are known to trigger asthma. The skilled artisan would have been able to combine two agents useful for preventing/treating asthma to achieve a composition which would be predicted to prevent or treat asthma.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Layla Bland
Patent Examiner
Art Unit 1623
August 14, 2007

Shaojia Anna Jiang
8/17/07
Supervisory Patent Examiner
Art Unit 1623
August 14, 2007